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09/584,978	06/02/2000	Dr. Rudi Neirinckx	44334	5707

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/584,978	Applicant(s) NEIRINCKX, DR. RUDI	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. With respect to the restriction and election of species requirement mailed August 28, 2001, the inventions of Groups I and II have been re-joined, and no election of species requirement will be made with respect to this re-joined group of claims. Accordingly, claims 1-8 have been examined together in their entirety.

Claims 9 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Applicant's election with traverse of the invention of Group II (extended in this Office action to include claims 1-8) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that all claims are directed to a formulation for treating psoriasis using EGF. This is not found persuasive because claims 9 and 10 do not use EGF. Rather, claims 9 and 10 are directed to the use of patentably distinct active agents, e.g., FGF, urogastrone, or fractions of the EGF molecule.

The requirement is still deemed proper and is therefore made FINAL.

2. The abstract of the disclosure is objected to because of the presence of legal and extraneous phraseology, especially in the second sentence of the Abstract. Further, the Abstract is insufficiently detailed as to the possible additional ingredients (e.g. sulfathiazone) and possible alternative ingredients (e.g., FGF and urogastrone). Correction is required. See MPEP § 608.01(b).

3. Claims 1, 2, 4, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2, and 8 are indefinite because it is not clear if these claims are drawn to compositions or to methods of use. The claims appear to be drawn to

methods due to the word "treatment" in each claim; however, none of the claims contain any positive process steps. See Ex parte Erlich, 3 USPQ2d 1011, 1017 (BPAI 1987). Claim 1 is indefinite because it is not clear if the formulations are to be limited to the particular forms recited in the parenthetical phrase or not. It is suggested that the parenthetical phrase could be deleted and made the subject matter of a dependent claim. Claims 4 and 7 are indefinite because the basis upon which the percentage concentrations are to be calculated, e.g., weight, volume, mole, is not specified.

4. Claims 1 and 8 are objected to because of the following informalities: Claim 1 would be clarified if the phrase "non-physiologic high" were to be re-written as "higher than physiological". Claim 8 would be clarified if "kg" were to be re-written as "kg body weight of the patient". Appropriate correction is required.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Much of the claimed subject matter is not recited in the specification. For example, the claimed recitations of formulations in general or of gels in particular; the concentrations recited in claims 2-4, 7, and 8; and the claimed optional additional or alternative components such as anti-inflammatory products, dermatologically-beneficial products, FGF, products with biological actions similar to EGF, urogastrone, and fractions of the EGF molecule; are not recited in the specification.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by the Nanney et al article (J. Invest. Dermatol., Vol. 98, pages 296-301). The Nanney et al article teaches treating psoriasis by topically administering sufficient EGF to downregulate EGF-R. In particular, the Nanney et al article teaches creams comprising 10 and 50 μg/ml EGF. See, e.g., the Abstract and page 29, column 1, third full paragraph.

8. Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 0 339 905. The European Patent Application '905 teaches the administration of growth factors, preferably EGF, for the treatment of wounds, including psoriasis. The EGF can be administered internally or topically, and its topical form includes creams. See, e.g., page 3, line 50 - page 4, line 8; page 4, lines 41-43; and Examples 1 and 2. The European Patent

Application '905 does not specifically exemplify the treatment of psoriasis with EGF, and does not teach Applicant's claimed EGF concentrations. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to administer EGF either internally or topically in the treatment of psoriasis, because it is desirable in the art to be able to treat psoriasis and because the European Patent Application '905 teaches that psoriasis is a type of wound which growth factors such as EGF would have been expected to be useful in treating. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations and dosages for the active agents of the European Patent Application '905 because drug concentration and dosage are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

9. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being obvious over the Nanney et al article (J. Invest. Dermatol., Vol. 98, pages 296-301) as applied against claims 1-3 above or the European Patent Application 0 339 905 as applied against claims 1-3 and 8 above, each further in view of the Phan et al article (Lancet, Vol. 348, page 547). The Nanney et al article and the European Patent Application '905 teach or suggest treating psoriasis with EGF, but do not teach using the EGF in combination with sulfadiazine. The Phan et al article teaches treating a severe case of psoriasis using a combination of active ingredients including silver sulfadiazine 1% cream. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use a combination of the EGF of the Nanney et al article or the European Patent Application '905 with the silver sulfadiazine 1% cream of the Phan et al article because it is prima facie obvious to use combinations of ingredients each of which has been used

individually for the same purpose (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), because the Phan et al article teaches that it is known to use combinations of active ingredients in order to treat severe cases of psoriasis, and because combining the silver sulfadiazine of the Phan et al article with the EGF of the Nanney et al article or the European Patent Application '905 would permit the EGF of the Nanney et al article or the European Patent Application '905 to be used for the treatment of severe cases of psoriasis.

10. Claims 2, 5, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hersch et al (U.S. Patent No. 6,337,320). Hersch et al teach topical formulations comprising EGF, anti-inflammatory products such as vitamin E, and other dermatologically-beneficial products. EGF concentrations can be 0.0025 wt % (= 25μg/g). See, e.g., column 10, lines 30-38; Examples 4, 6, and 7; column 22, lines 13-15; and column 24, lines 40-52. With respect to the intended use limitation set forth in instant claim 6, an intended use limitation does not impart patentability to a composition claim where the composition is otherwise anticipated by or obvious over the prior art.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being obvious over Hersch et al (U.S. Patent No. 6,337,320). Application of Hersch et al is the same as in the above rejection of claims 2, 5, and 6. Hersch et al do not teach Applicant's claimed EGF concentrations. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations and dosages for the active agents of Hersch et al because drug concentration and dosage are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

12. Njieha et al (U.S. Patent No. 5,070,188, see especially column 1, lines 18-20, and column 5, lines 10-12) and Cini et al (U.S. Patent No. 5,130,298, see especially column 5, lines 28-34) are cited as art of interest, being essentially duplicative of the references applied above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

February 26, 2003